

EXHIBIT 6



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
087845,657	04/25/97	JANG	6 18461.709

3CM1/0127
 PAUL DAVIS
 WILSON SONSINI GOODRICH & ROSATI
 650 PAGE MILL ROAD
 PALO ALTO CA 94304-1050

EXAMINER	
NGUYEN, T	
ART UNIT	PAPER NUMBER
3308	

DATE MAILED: 01/27/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

PTOL-90 (Rev. 6/94)

1 - PATENT APPLICATION FILE COPY

CM 000163

Office Action Summary		Application No. 08/845,657	Applicant(s) JANG
		Examiner Tram Nguyen	Group Art Unit 3308

☒ Responsive to communication(s) filed on Apr 25, 1997.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-86 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5, 7-18, 21, 24-30, 39-45, 48-50, 52-58, 60-62, 64, 66-73, 76, and 77 are rejected.

☒ Claim(s) 4, 6, 19, 20, 22, 23, 31-38, 46, 47, 51, 59, 63, 65, 74, 75, 77, 78, and 80-86 are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

U. S. Patent and Trademark Office
PTO-326 (Rev. 9-95)

Office Action Summary

Part of Paper No. 5

CM 000164

Serial Number: 08/845,657
Art Unit: 3308

Page 2

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

2. The disclosure is objected to because of the following informalities:
 - (a) On page 1, lines 5-16 contain blank spaces which need to be filled in with the appropriate information. In line 27, replace "alterative" with -- alternative --.
 - (b) On page 4, line 10, replace "axio-lateral" with -- axio-laterally --.
 - (c) On page 16, line 19, after "way" insert -- to --.
 - (d) On page 17, line 11, replace "Reenforcement" with -- reenforcement --.Appropriate correction is required.

Claim Objections

3. Claims 3-6 are objected to because of the following informalities:
 - (a) Regarding claims 3-6, applicant should delete the "column" from "first expansion column strut pair" and "second column expansion strut pair", to keep claim terminology consistent with claim 1 upon which these claims depend. Appropriate correction is required.

Serial Number: 08/845,657
Art Unit: 3308

Page 3

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 7-18, 21, 24-30, 39-45, 48-50, 52-58, 60-62, 64, 66-73, 76 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchasik et al. (EP 079 067 A2), for the following reasons:

(a) With respect to claims 1, 5, 16, 18, 24-29, 39, 40, 44, 45, 48, 50, 52-56, 58, 66, 71, 72, and 76, see refer to the modified Figure 2 attached to this office action, wherein:

20A represents the first expansion column;

20B represents the second expansion column;

20C represents the third expansion column;

30A represents the first connecting strut column; and

30B represents the second connecting strut column.

(b) With respect to claims 7-12, in so far as applicant has not recited any particular radius of curvature or slant angle, please refer to the modified Figure 2 attached to this office action.

(c) With respect to claims 17 and 57, please refer to the modified Figure 2 attached to this office action, wherein $m = 2$.

Serial Number: 08/845,657
Art Unit: 3308

Page 4

- (d) With respect to claims 21 and 64, please refer to the modified Figure 2 attached to this office action, wherein the far left edge defines the first reinforcement column, and the far right edge defines the second reinforcement column.
- (e) With respect to claims 30 and 70, please refer to the modified Figure 2 attached to this office action, wherein at least a portion within the configurations are symmetrical.
- (f) With respect to claims 2, 41-43, 49, 60-62, 67-69, and 73, please refer to Figure 2A of Pinchasik et al.
- (g) With respect to claim 79, in so far as this stent formed from etched sheet metal which expands when pressure is internally applied (col. 1, lines 5-8 and col. 2, lines 25-33), it is inherent that the stent is configured to be positioned at an exterior of an expandable balloon.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchasik et al. '067 in view of Lam et al. (EP 0 679 372 A2), for the following reasons:

With respect to claims 13-15, Pinchasik et al. discloses the invention substantially as claimed (please refer to the modified Figure 2 attached to this office action). However, Pinchasik et al. fails to disclose that at least the ends of the stent include an electroplated material for use as

Serial Number: 08/845,657
Art Unit: 3308

Page 5

a radiopaque marker. Lam et al. teaches plating the ends of an expandable stent with gold for use as a radiopaque marker (col. 2, lines 13-58 and col. 3, lines 1-15) so that the location, length, and diameter of the stent can be determined under fluoroscopy. It would have been obvious to one of ordinary skill in the art at the time of the invention to have goldplated the ends of the expandable stent of Pinchasik et al., as taught by Lam et al., so that the location, length, and diameter of the stent can be determined under fluoroscopy.

Allowable Subject Matter

8. Claims 4, 6, 19, 20, 22, 23, 31-38, 46, 47, 51, 59, 63, 65, 74, 75, 77, 78, and 80-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fischell et al. (U.S. Patent No. 5,697,971), Fischell et al. (U.S. Patent No. 5,695,516), Klein (U.S. Patent No. 5,593,442), Orth et al. (U.S. Patent No. 5,591,197), and Miksza (EP 606 165 A1) all show various features of the claimed invention.

Serial Number: 08/845,657
Art Unit: 3308

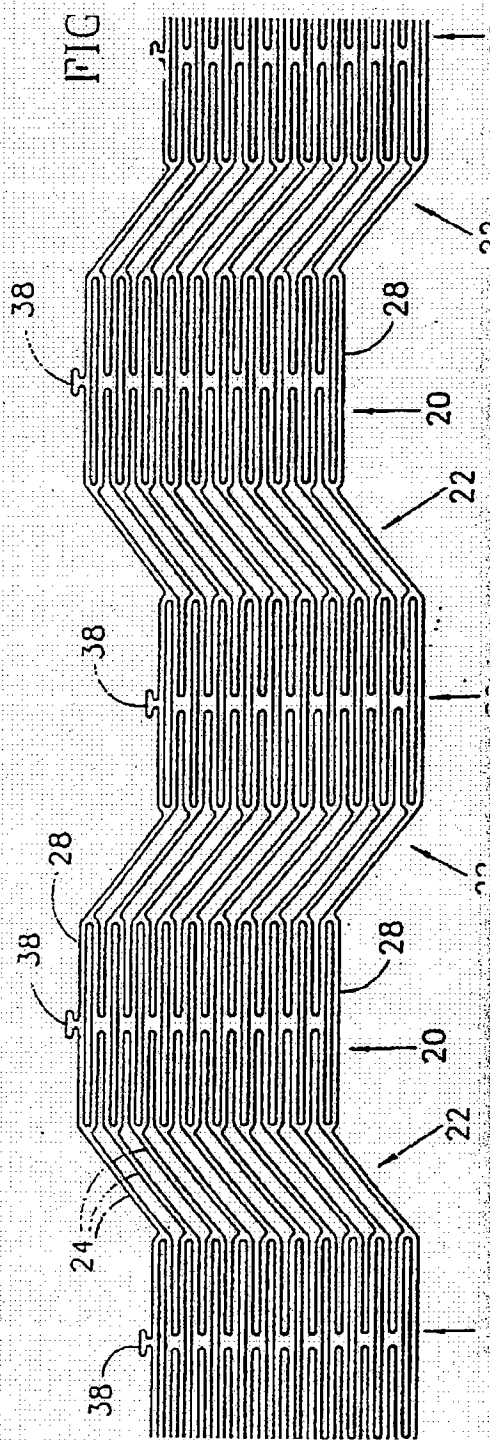
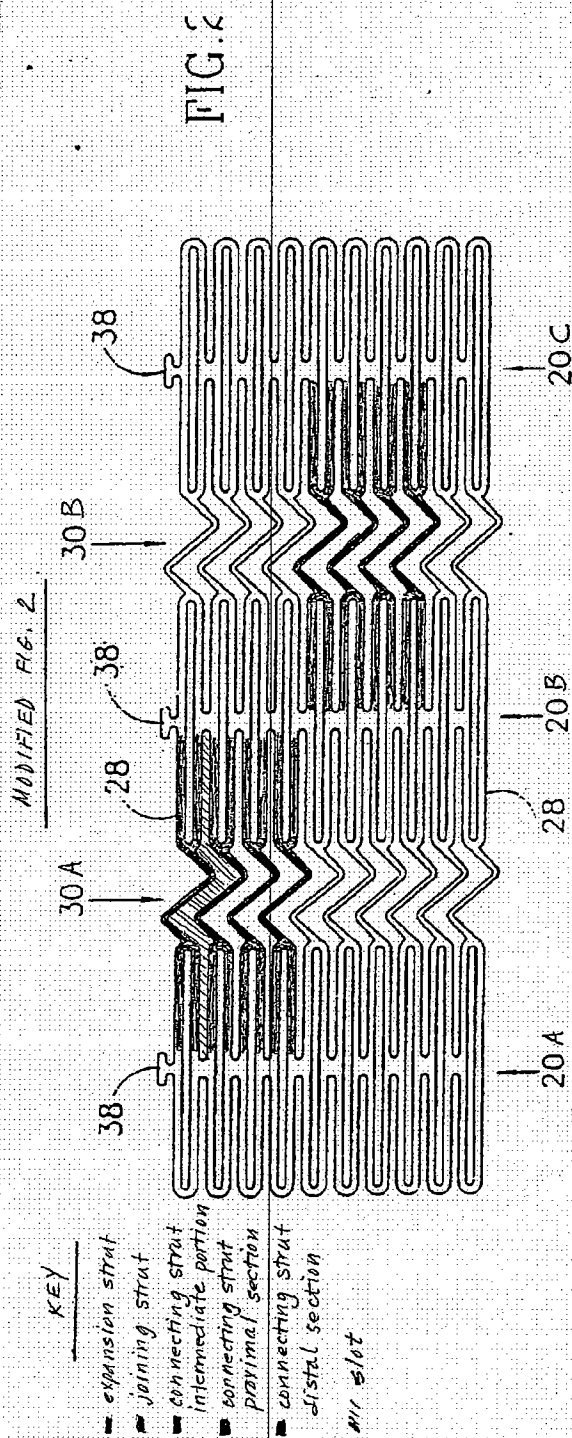
Page 6

Any inquiry concerning this communication or earlier communications regarding this application should be directed to Tram Nguyen at (703) 308-0804/(703)305-3590 (FAX). If you are unable to reach me, please contact my supervisor, John Weiss, at (703) 308-2702. In a case requiring immediate assistance, please call (703) 308-0858 to reach the main operator.

Tan
TAN
January 20, 1998

Michael J. Milano
MICHAEL J. MILANO
PRIMARY EXAMINER
ART UNIT 3308

CM 000169





#7/a
7/7
XB

Attorney Docket No. 18461-709

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jang

Application No. 08/845,657

Filed: April 25, 1997

For: INTRAVASCULAR STENT

Group Art Unit: 3308

Examiner: Nguyen, T.

RECEIVED

AMENDMENT

GROUP 3200

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Office Action mailed January 27, 1998, submitted on or before the current due date of June 27, 1998.

Applicant petitions the Commissioner for an extension of time of two months, from April 27, 1998 to June 27, 1998. The Commissioner is authorized to charge Deposit Account No. 23-2415 (18461-709) the amount of \$200.00 for a two month extension of time for a small entity.

Applicant's attorney thanks Examiners Nguyen and Willse for the many courtesies extended during the interview conducted on June 5, 1998.

In the Specification

Please amend the specification as follows:

Page 1, line 8

replace "_____ (Attorney Docket No. 17828.707)" with --
08/824,142--.

REPRIVATEWFOCSFDUANGI709.AMD

06/29/1998 65840484 00000012 232415 0045657

01 FC:215 200.00 CH

A

CM 000178

Application No. 08/845,657
Page 2

Page 1, line 10

replace "_____" (Attorney Docket No. 17828.708)" with --
08/824,866--.

Page 1, lines 12-13

replace "_____" (Attorney Docket No. 17828.709)" with --
08/824,865--.

Page 1, lines 14-15

replace "_____" (Attorney Docket No. 17828.708)" with --
08/845,734--.

Page 1, line 27

replace "alternative" with --alternative--.

Page 4, line 10

replace "axio-lateral" with --axio-laterally--.

Page 16, line 19

after "way" insert --to--.

Page 17, line 11

replace "Reenforcement" with --reenforcement--.

In the Claims

Please cancel claim 2.

Please amend the claims as follows:

1. (Amended) A stent in a non-expanded state, comprising:
a first expansion strut pair including a first expansion strut positioned
adjacent to a second expansion strut and a joining strut of the first expansion strut
pair that couples the first and second expansion struts at a distal end of the first
expansion strut pair, a plurality of the first expansion strut pair forming a first
expansion column;

H:\PRIVATE\W\DOCS\FUJANG\709.AMD

Application No. 08/845,657
Page 3

a' conl.

a second expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a plurality of the second expansion strut pair forming a second expansion column;

a first connecting strut including a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section, the first connecting strut proximal section being coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, [wherein a length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of] the first connecting strut intermediate section [is] being non-parallel to [greater than the length of] the first connecting strut proximal and distal sections, wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

a'

2/ (Amended) The stent of claim 1, wherein a spacing distance between the first expansion [column] strut pair and an adjacent first expansion [column] strut pair in the first expansion column are the same.

3/ (Amended) The stent of claim 1, wherein a spacing distance between the second [column] expansion strut pair and an adjacent second [column] expansion strut pair in the second expansion column are different.

H:\PRIVATE\BWP\DOCS\DUANG\009.AMD

46

Application No. 08/845,657
Page 4

4 5. (Amended) The stent of claim 1, wherein a spacing distance between the first expansion [column] strut pair and an adjacent first expansion [column] strut pair in the first expansion column, and a spacing distance between the second [column] expansion strut pair and an adjacent second [column] expansion strut pair in the second expansion column are the same.

5 6. (Amended) The stent of claim 1, wherein a spacing distance between the first expansion [column] strut pair and an adjacent first expansion [column] strut pair in the first expansion column, and a spacing distance between the second [column] expansion strut pair and an adjacent second [column] expansion strut pair in the second expansion column are different.

23 24. (Amended) A stent in a non-expanded state, comprising:
a first expansion column formed of a plurality of first expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled

H:\PRIVATE\WPD\CS\PD\JANG\709.AMD

CM 000181

Application No. 08/845,657
Page 5

to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut;

a second expansion column formed of a plurality of second expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining

HA\PRIVATE\WP\DOCS\PD\JANG\709.AMD

Application No. 08/845,657
Page 6

strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a first connecting strut column formed of a plurality of first connecting struts, each connecting strut of the first connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column, [wherein a length of the connecting strut proximal section is the same as a length of the connecting strut distal section and the connecting strut intermediate section has a length that is greater than the lengths of the connecting strut distal and proximal sections], the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections, wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

H:\PRIVATE\WPDOS\PD\JANG\709.AMD

CM 000183

Application No. 08/845,657
Page 7

REMARKS

The Examiner has objected to the disclosure because of informalities and typographical errors, and requires correction. The Examiner has also objected to dependent claims 3-6 because of informalities and requires correction. Applicant has amended the specification and claims 3-6 to overcome these grounds of objection.

Applicant thanks the Examiner for his indication that claims 4, 6, 19, 20, 22, 23, 31-38, 46-47, 51, 59, 63, 65, 74-75, 77-78 and 80-86 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-3, 5, 7-18, 21, 24-30, 39-45, 48-50, 52-58, 60-62, 64, 66-73, 76 and 79 have been rejected under 35 U.S.C. § 102(b) as anticipated by EP 079067A2 ("Pinchasik, et al."). Claims 13-15 stand rejected under 35 U.S.C. § 103 as being obvious over Pinchasik, et al. in view of EP 0679372A2 ("Lam, et al."). These grounds of rejection are respectively traversed.

The present invention is a stent with a first connecting strut with proximal, distal and intermediate sections. The intermediate section is non-parallel to the proximal and distal sections. Additionally, the stent has a first expansion strut of a first expansion strut pair in a first expansion column that has a longitudinal axis which is offset from a longitudinal axis of a first expansion strut of the second expansion strut pair in a second expansion column.

Pinchasik et al., fails to teach or suggest such a structure. Pinchasik et al., in combination with Lam et al., also fails to teach or suggest such a structure. Additionally, there is no suggestion or motivation to combine the teachings of Pinchasik et al., with Lam et al. to obtain the stent of the present invention.

H:\PRIVATE\WPDOCS\EDVANG\08.AMD

Application No. 08/845,657
Page 8

CONCLUSION

Applicant believes that the application is now in condition for allowance
and respectfully requests issuance of a notice of allowance.

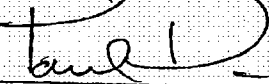
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Date:

6/17/98

By:



Paul Davis, Reg. No. 29,294

650 Page Mill Road
Palo Alto, California 94304
(415) 493-9300

H:\PRIVATE\W\DOCS\PD\JANG\09.AMD

CM 000185

EXHIBIT 7



US005514154A

United States Patent [19]

Lau et al.

[11] **Patent Number:** **5,514,154**[45] **Date of Patent:** **May 7, 1996**[54] **EXPANDABLE STENTS**

[75] **Inventors:** Lilip Lau, Sunnyvale; William M. Hartigan, Fremont; John J. Frantzen, Copperopolis, all of Calif.

4,969,458 11/1990 Wiktor 606/194
 4,994,071 2/1991 MacGregor 606/194
 5,102,417 4/1992 Palmaz 606/195
 5,195,984 3/1993 Schatz 606/193
 5,356,433 10/1994 Rowland et al. 623/11

[73] **Assignee:** Advanced Cardiovascular Systems, Inc., Santa Clara, Calif.

Primary Examiner—Christopher A. Bennett

Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht

[21] **Appl. No.:** 281,790

[22] **Filed:** Jul. 28, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 164,986, Dec. 9, 1993, abandoned, which is a continuation of Ser. No. 783,558, Oct. 28, 1991, abandoned.

[51] **Int. Cl.⁶** A61M 29/00

[52] **U.S. Cl.** 606/195; 606/194; 606/108; 623/13

[58] **Field of Search** 606/191–198, 606/108; 604/93, 96, 97, 280, 282, 283; 623/1, 11, 12

[57]

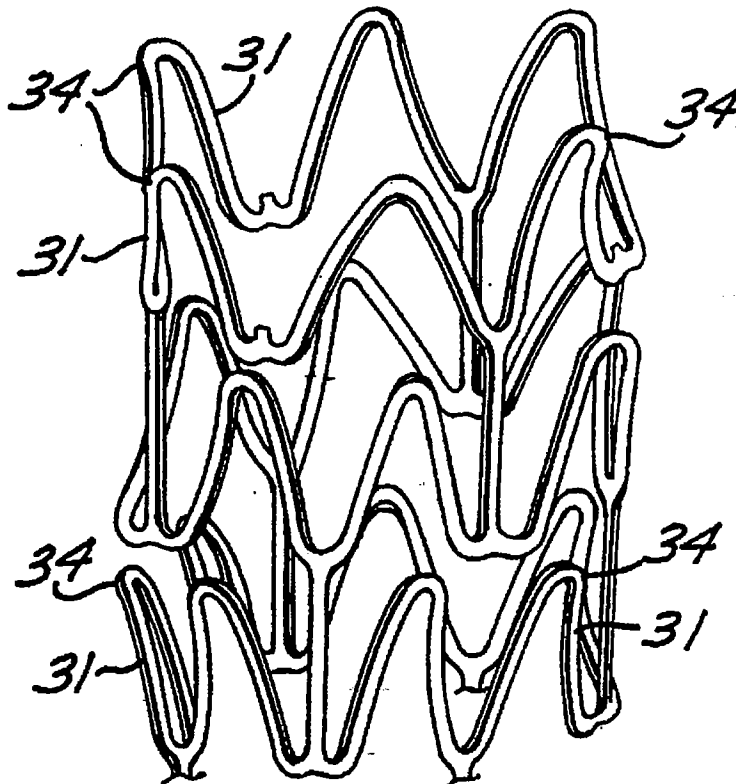
ABSTRACT

The invention is directed to an expandable stent for implantation in a body lumen, such as an artery, and a method for making it from a single length of tubing. The stent consists of a plurality of radially expandable cylindrical elements generally aligned on a common axis and interconnected by one or more interconnective elements. The individual radially expandable cylindrical elements consist of ribbon-like material disposed in an undulating pattern. Portions of the expanded stent project outwardly into engagement with the vessel wall to more securely attach the stent.

[56] **References Cited****U.S. PATENT DOCUMENTS**

4,776,337 10/1988 Palmaz 623/1

23 Claims, 4 Drawing Sheets



U.S. Patent

May 7, 1996

Sheet 1 of 4

5,514,154

FIG. 1

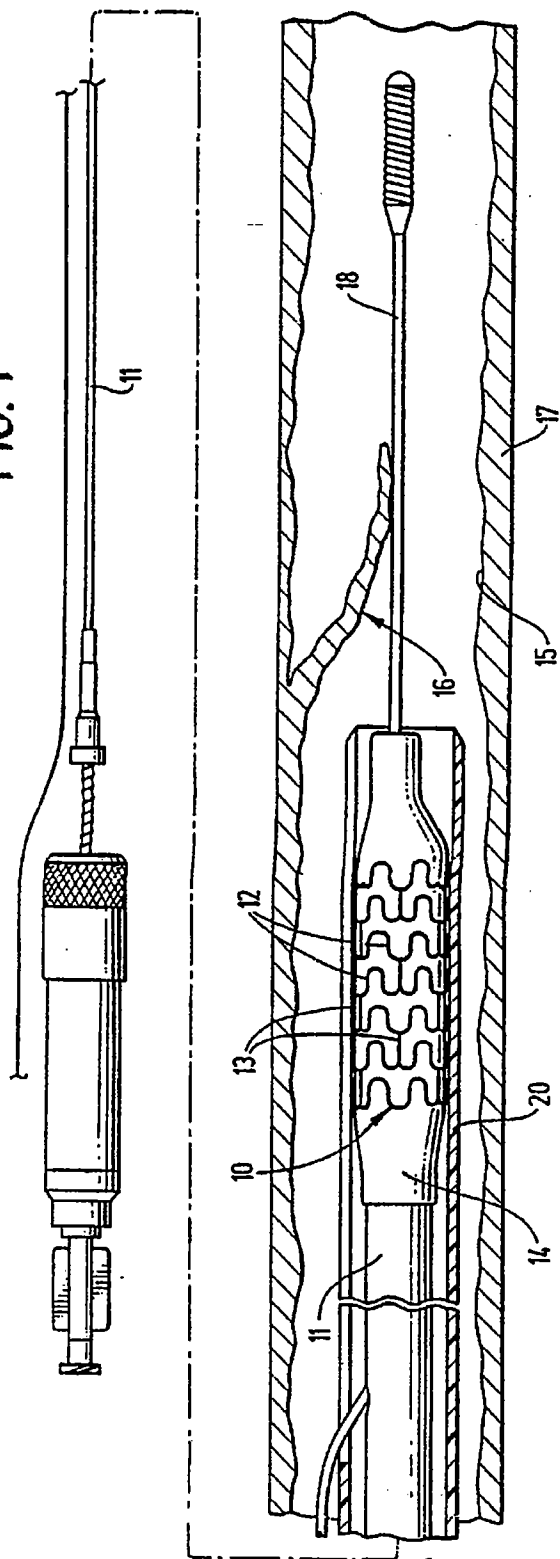


FIG. 3

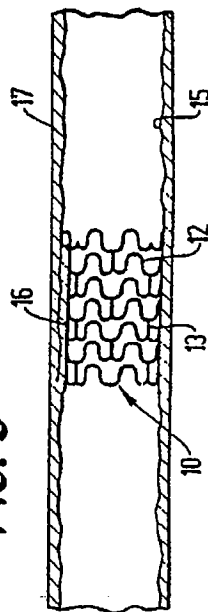
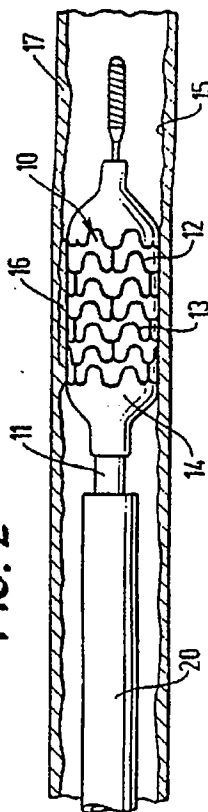


FIG. 2



U.S. Patent

May 7, 1996

Sheet 2 of 4

5,514,154

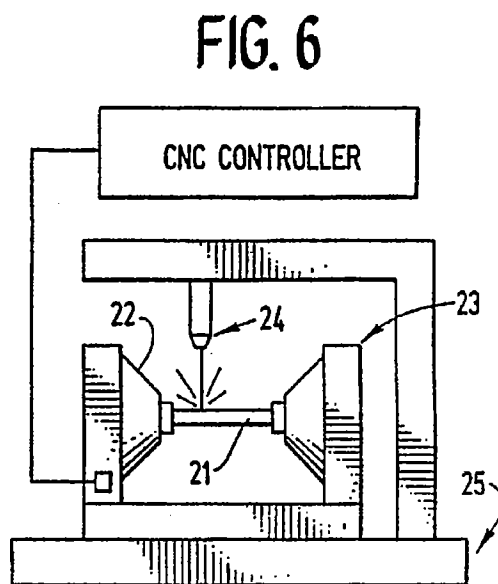
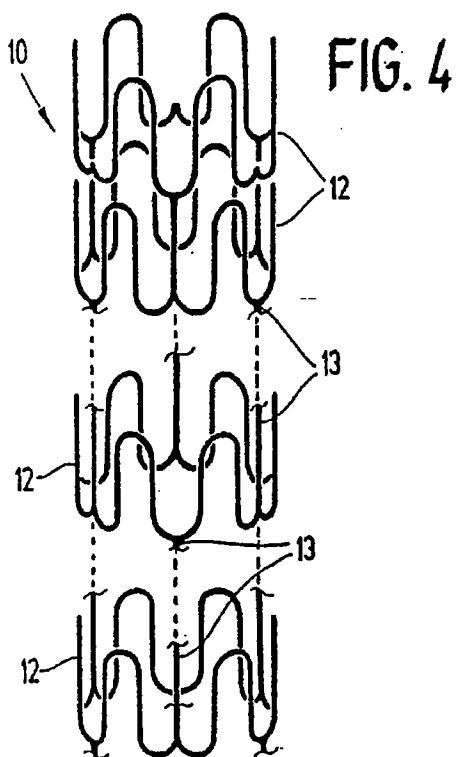
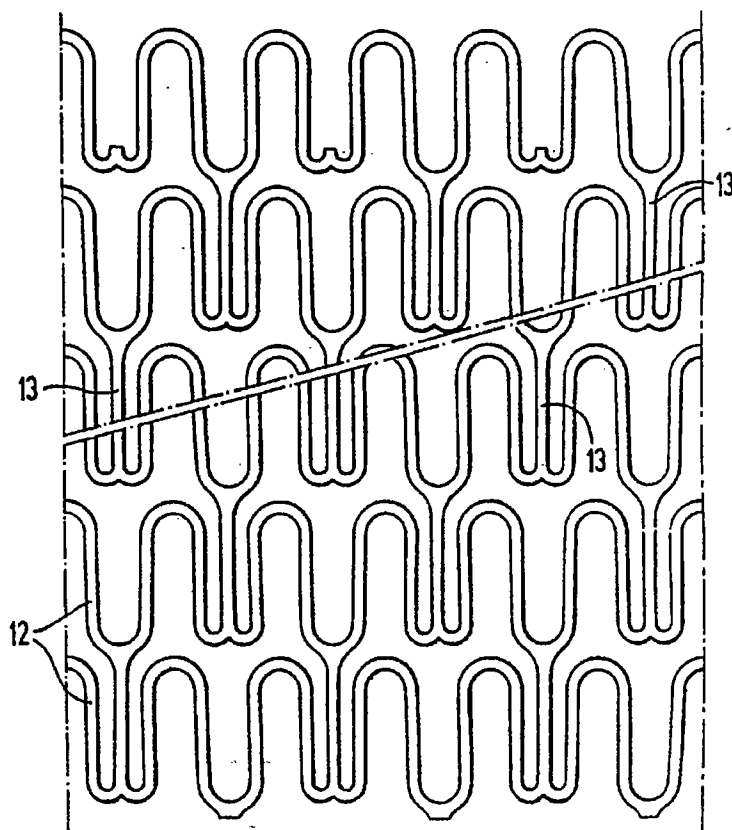


FIG. 5



U.S. Patent

May 7, 1996

Sheet 3 of 4

5,514,154

FIG. 7

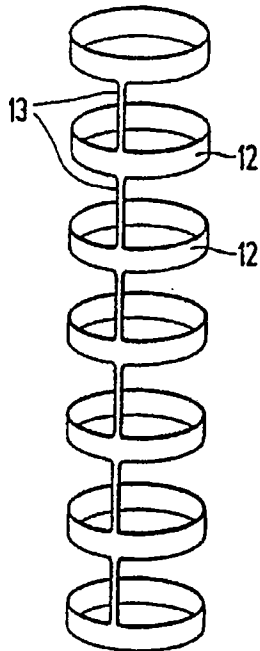


FIG. 8

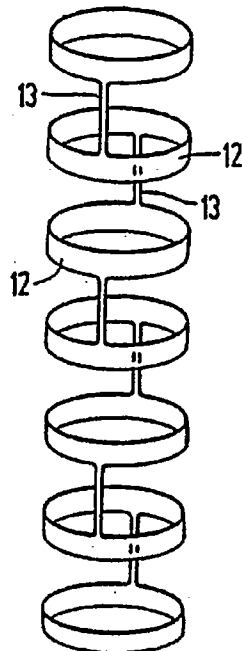


FIG. 9

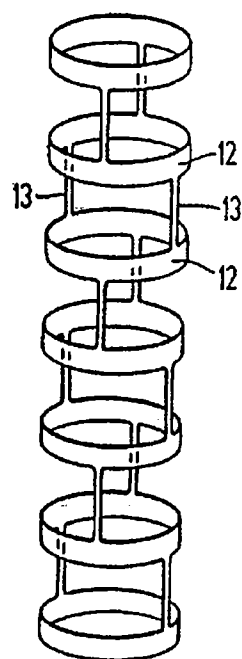


FIG. 10

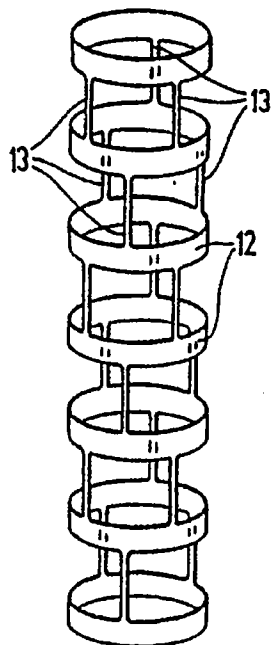
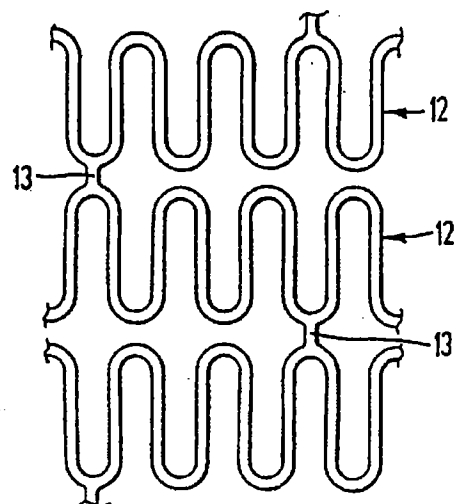


FIG. 11



U.S. Patent

May 7, 1996

Sheet 4 of 4

5,514,154

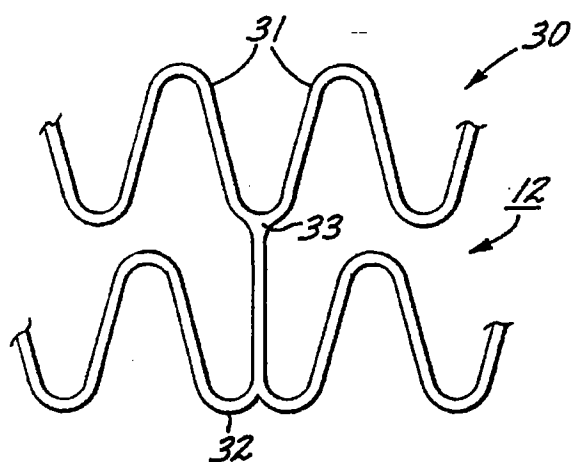


FIG. 12

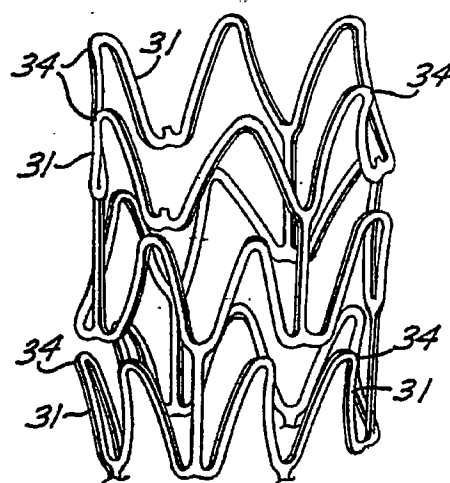


FIG. 13

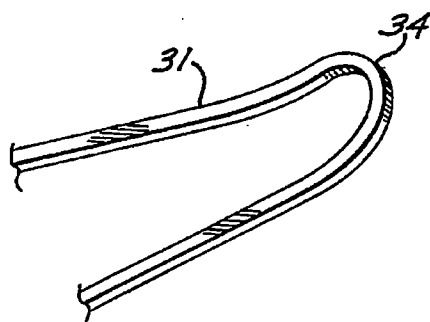


FIG. 14

5,514,154

1

EXPANDABLE STENTS**RELATED APPLICATIONS**

This application is a continuation-in-part of U.S. patent application U.S. Ser. No. 08/164,986 filed Dec. 9, 1993, now abandoned, which is a continuation application of U.S. Ser. No. 07/783,558 filed Oct. 28, 1991, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to expandable endoprosthesis devices, generally called stents, which are adapted to be implanted into a patient's body lumen, such as blood vessel, to maintain the patency thereof. These devices are very useful in the treatment of atherosclerotic stenosis in blood vessels.

Stents are generally tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. They are particularly suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway therethrough.

Further details of prior art stents can be found in U.S. Pat. No. 3,868,956 (Alfidi et al.); U.S. Pat. No. 4,512,338 (Balko et al.); U.S. Pat. No. 4,553,545 (Maass et al.); U.S. Pat. No. 4,733,665 (Palmaz); U.S. Pat. No. 4,762,128 (Rosenbluth); U.S. Pat. No. 4,800,882 (Gianturco); U.S. Pat. No. 4,856,516 (Hillstead); and U.S. Pat. No. 4,886,062 (Wiktor), which are hereby incorporated herein in their entirety by reference thereto.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter. One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery.

What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which it expanded. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein.

The stent of the invention generally includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and a preferable position to prevent warping of the stent upon the expansion

2

thereof. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, but not so close as to compromise the longitudinal flexibilities of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but is still very stiff in the radial direction in order to resist collapse.

The stent embodying features of the invention can be readily delivered to the desired luminal location by mounting it on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stent to the expandable member on the catheter for delivery to the desired location are available. It is presently preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, or using bioresorbable temporary adhesives.

The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention generally circumferential undulating pattern, e.g. serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an aspect ratio of about two to one to about 0.5 to one. A one to one aspect ratio has been found particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern thereof similar to changes in a waveform which result from decreasing the waveform's amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded (except with NiTi alloys) so that the stent will remain in the expanded condition and, therefore, they must be sufficiently rigid when expanded to prevent the collapse thereof in use. During expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed in the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

With superelastic NiTi alloys, the expansion occurs when the stress of compression is removed so as to allow the phase transformation from austenite back to martensite and as a result the expansion of the stent.

The elongated elements which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed in a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting

5,514,154

3

elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent. In this manner there is no shortening of the stent upon expansion.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site.

In a presently preferred embodiment of the invention the stent is conveniently and easily formed by coating stainless steel tubing with a material resistant to chemical etching, removing portions of the coating to expose portions of underlying tubing which are to be removed to develop the desired stent structure. The exposed portions of the tubing are removed by chemically etching from the tubing exterior leaving the coated portion of the tubing material in the desired pattern of the stent structure. The etching process develops smooth openings in the tubing wall without burrs or other artifacts which are characteristic of mechanical or laser machining processes in the small sized products contemplated. Moreover, a computer controlled laser patterning process to remove the chemical resistive coating makes photolithography technology adaptable to the manufacture of these small products. The forming of a mask in the extremely small sizes needed to make the small stents of the invention would be a most difficult task. A plurality of stents can be formed from one length of tubing by repeating the stent pattern and providing small webs or tabs to interconnect the stents. After the etching process, the stents can be separated by severing the small webs or tabs which connect them.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention. When taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery.

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall.

FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter.

FIG. 4 is a perspective view of a stent embodying features of the invention in an unexpanded state, with one end of the stent being shown in an exploded view illustrating the details thereof.

FIG. 5 is a plan view of a flattened section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. 4.

FIG. 6 is a schematic representation of equipment for selectively removing coating applied to tubing in the manufacturing of the stents of the present invention.

4

FIGS. 7 through 10 are perspective views schematically illustrating various configurations of interconnective element placement between the radially expandable cylindrical elements of the stent.

FIG. 11 is a plan view of a flattened section of a stent illustrating an alternate undulating pattern in the expandable cylindrical elements of the stent which are out of phase.

FIG. 12 is an enlarged partial view of the stent of FIG. 5 with the various members slightly expanded.

FIG. 13 is a perspective view of the stent of FIG. 4 after it is fully expanded depicting some members projecting radially outwardly.

FIG. 14 is an enlarged, partial perspective view of one U-shaped member with its tip projecting outwardly after expansion.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a stent 10 incorporating features of the invention which is mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 15. The artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20 as described in co-pending applications Ser. No. 07/647,464 filed on Apr. 25, 1990 and entitled STENT DELIVERY SYSTEM may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevent abrasion of the body lumen by the open surface of the stent 20 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon.

Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g. tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10 onto the exterior of the balloon. The catheter-stent assembly is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed across the damaged arterial section with the detached or dissected lining 16 and then the catheter-stent assembly is advanced over a guidewire 18 within the artery

5,514,154

5

15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid there-through.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of stent 10 which are pressed into the wall of the artery 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 are preferably placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4 the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120 degrees apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60 degrees from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible, and several examples are illustrated schematically in FIGS. 7-10. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion thereof.

FIG. 10 illustrates a stent of the present invention wherein three interconnecting elements 12 are disposed between radially expandable cylindrical elements 11. The interconnecting elements 12 are distributed radially around the circumference of the stent at a 120-degree spacing. Disposing four or more interconnecting elements 13 between adjacent cylindrical elements 12 will generally give rise to the same considerations discussed above for two and three interconnecting elements.

The properties of the stent 10 may also be varied by alteration of the undulating pattern of the cylindrical elements 13. FIG. 11 illustrates an alternative stent structure in which the cylindrical elements are in serpentine patterns but out of phase with adjacent cylindrical elements. The particular pattern and how many undulations per unit of length around the circumference of the cylindrical element 13, or

6

the amplitude of the undulations, are chosen to fill particular mechanical requirements for the stent such as radial stiffness.

The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g. at the peaks of the undulations or along the sides of the undulations as shown in FIGS. 5 and 11.

In keeping with the invention, and with reference to FIGS. 4 and 12-14, cylindrical elements 12 are in the form of a serpentine pattern 30. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. Serpentine pattern 30 is made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members.

As depicted in FIGS. 13 and 14, after cylindrical elements 12 have been radially expanded, outwardly projecting edges 34 are formed. That is, during radial expansion U-shaped members 31 will tip outwardly thereby forming outwardly projecting edges. These outwardly projecting edges provide for a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall. In other words, outwardly projecting edges embed into the vascular wall, for example artery 15, as depicted in FIG. 3. Depending upon the dimensions of stent 10 and the thickness of the various members making up the serpentine pattern 30, any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outwardly to form a projecting edge 34. It is most likely and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly.

The stent 10 of the present invention can be made in many ways. However, the preferred method of making the stent is to coat a thin-walled tubular member, such as stainless steel tubing, with a material which is resistive to chemical etchants, remove portions of the coating to expose underlying tubing which is to be removed but to leave coated portions of the tubing in the desired pattern for the stent so that subsequent etching will remove the exposed portions of the metallic tubing, but will leave relatively untouched the portions of the metallic tubing which are to form the stent. The coated portion of the metallic tube is in the desired shape for the stent. An etching process avoids the necessity of removing burrs or slag inherent in conventional or laser machining process. It is preferred to remove the etchant-resistive material by means of a machine-controlled laser as illustrated schematically in FIG. 6.

A coating is applied to a length of tubing which, when cured, is resistive to chemical etchants. "Blue Photoresist" made by the Shipley Company in San Jose, Calif., is an example of suitable commercially available photolithographic coatings. The coating is preferably applied by electrophoretic deposition.

To ensure that the surface finish is reasonably uniform, one of the electrodes used for the electrochemical polishing is a doughnut-shaped electrode which is placed about the central portion of the tubular member.

The tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers. The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch in the unexpanded condition, the same outer

5,514,154

7

diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inch or more. The wall thickness of the tubing is about 0.003 inch. In the instance when the stent was plastic, it would have to be heated within the arterial site where the stent is expanded to facilitate the expansion of the stent. Once expanded, it would then be cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or the balloon directly by a suitable system such as disclosed in a co-pending application Ser. No. 07/521,337, filed Jan. 26, 1990 entitled DILATATION CATHETER ASSEMBLY WITH HEATED BALLOON which is incorporated herein in its entirety by reference. The stent may also be made of materials such as superelastic NiTi alloys such as described in co-pending application Ser. No. 07/629,381, filed Dec. 18, 1990, entitled SUPERELASTIC GUIDING MEMBER which is incorporated herein in its entirety by reference. In this case the stent would be formed full size but deformed (e.g. compressed) into a smaller diameter onto the balloon of the delivery catheter to facilitate transfer to a desired intraluminal site. The stress induced by the deformation transforms the stent from a martensite phase to an austenite phase and upon release of the force, when the stent reaches the desired intraluminal location, allows the stent to expand due to the transformation back to the martensite phase.

Referring to FIG. 6, the coated tubing 21 is put in a rotatable collet fixture 22 of a machine controlled apparatus 23 for positioning the tubing 21 relative to a laser 24. According to machine-encoded instructions, the tubing 21 is rotated and moved longitudinally relative to the laser 24 which is also machine controlled. The laser selectively removes the etchant-resistive coating on the tubing by ablation and a pattern is formed such that the surface of the tube that is to be removed by a subsequent chemical etching process is exposed. The surface of the tube is therefore left coated in the discrete pattern of the finished stent.

A presently preferred system for removing the coating on the tubing includes the use of an 80-watt CO₂ laser, such as a Coherent Model 44, in pulse mode (0.3 mS pulse length); 48 mA key current and 48 W key power with 0.75 W average power, at 100 Hz; Anorad FR=20; 12.5 Torr; with no assist gas. Low pressure air is directed through the fine focus head to ensure that no vapor contacts the lens. The assist gas jet assembly on the laser unit may be removed to allow a closer proximity of the fine focus head and the collet fixture. Optimum focus is set at the surface of the tubing. Cured photo-resist coating readily absorbs the energy of the CO₂ wavelength, so that it can be readily removed by the laser. A coated 4-inch length of 0.06 inch stainless steel tubing is preferred and four stents can be patterned on the length of tubing. Three tabs or webs between stents provide good handling characteristics for the tubing after the etching process.

The process of patterning the resistive coating on the stent is automated except for loading and unloading the length of tubing. Referring again to FIG. 6 it may be done, for example, using a CNC-opposing collet fixture 22 for axial rotation of the length of tubing, in conjunction with a CNC X/Y table 25 to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the CO₂ laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating, but is otherwise conventional.

This process makes possible the application of present photolithography technology in manufacturing the stents.

8

While there is presently no practical way to mask and expose a tubular photo-resist coated part of the small size required for making intravascular stents, the foregoing steps eliminate the need for conventional masking techniques.

After the coating is thus selectively ablated, the tubing is removed from the collet fixture 22. Next, wax such as ThermoCote N-4 is heated to preferably just above its melting point, and inserted into the tubing under vacuum or pressure. After the wax has solidified upon cooling, it is reheated below its melting point to allow softening, and a smaller diameter stainless steel shaft is inserted into the softened wax to provide support. The tubing is then etched chemically in a conventional manner. After cutting the tabs connecting the stents any surface roughness or debris from the tabs is removed. The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO CO., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110–135 degrees F. and the current density is about 0.4 to about 1.5 amps per in.² Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications and improvements may be made without departing from the scope of the invention.

Other modifications and improvements can be made to the invention without departing from the scope thereof.

What is claimed is:

1. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other; and

an outer wall surface on said cylindrical elements, said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter.

2. The stent of claim 1, wherein said outer wall surface is substantially smooth when said stent in said first diameter configuration and said outwardly projecting edges form only as said stent is expanded radially outwardly from said first diameter to said second, enlarged diameter.

3. The stent of claim 1, wherein said plurality of outwardly projecting edges extend radially outwardly from said outer wall surface and embed in the vascular wall of the body lumen in order to more firmly attach said stent to the vascular wall.

4. The stent of claim 1, wherein said plurality of cylindrical elements include a plurality of peaks and valleys having a serpentine pattern.

5. The stent of claim 4, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality

5,514,154

9

of Y-shaped members, and a plurality of W-shaped members, whereby a portion of said Y-shaped members forms said plurality of said connecting elements.

6. The stent of claim 5, wherein at least some of said plurality of said U-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

7. The stent of claim 5, wherein at least some of said plurality of U-shaped, W-shaped, and Y-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

8. The stent of claim 1, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

9. The stent of claim 1, wherein said stent is formed of a biocompatible material selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers.

10. The stent of claim 1, wherein said stent is formed from a single piece of tubing.

11. The stent of claim 1, wherein said stent is coated with a biocompatible coating.

12. A longitudinally flexible stent, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be concentrically aligned on a common longitudinal axis; and

a plurality of generally parallel connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, so that said stent, when expanded radially outwardly, retains its overall length without appreciable shortening.

13. The stent of claim 12, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

14. The stent of claim 12, wherein said radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof.

15. The stent of claim 14, wherein said stent is formed of a biocompatible material selected from the group consisting of stainless steel, tantalum, super-elastic NiTi alloys, and thermoplastic polymers.

10

16. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are in axial alignment.

17. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are circumferentially displaced with respect to said longitudinal axis.

18. The stent of claim 17, wherein the circumferential displacement of said connecting elements between adjacent cylindrical elements is uniform.

19. The stent of claim 12, wherein there are up to four of said connecting elements disposed between adjacent radially expandable cylindrical elements.

20. The stent of claim 12, wherein said radially expandable cylindrical elements and said connecting elements are made of the same material.

21. The stent of claim 12, wherein said stent is formed from a single piece of tubing.

22. The stent of claim 12, wherein the stent is coated with a biocompatible coating.

23. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other;

an outer wall surface on said cylindrical elements, said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter, whereby said stent does not substantially shorten upon expansion from said first diameter to said second, larger diameter.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,514,154

DATED : May 7, 1996

INVENTOR(S) : Lilip Lau, William M. Hartigan, John J. Frantzen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, Line 3, Change "for", To read --form--.

Column 3, Line 41, Change "invention. When", To read --invention, when--.

Column 4, Line 46, Change "20", To read --10--.

Column 5, Line 53 and Line 55, Change "12", To read --13--.

Column 5, Line 54, Change "11", To read --12--.

Column 5, Line 63 and Line 67, Change "13", To read --12--.

Column 8, Line 33, Remove entire paragraph that begins with "Other".

Signed and Sealed this

Twenty-fourth Day of March, 1998

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBITS 8-11
REDACTED IN FULL

CERTIFICATE OF SERVICE

I, Adam W. Poff, Esquire, hereby certify that on May 25, 2007, I caused to be served a true and correct copy of the foregoing document upon the following counsel of record as indicated.

BY HAND DELIVERY


Steven J. Balick, Esquire
John G. Day, Esquire
Lauren E. Maguire, Esquire
Ashby & Geddes
500 Delaware Avenue, 8th Floor
Wilmington, DE 19899

BY FEDEX & E-MAIL

Gregory L. Diskant, Esquire
Eugene M. Gelernter, Esquire
Kathleen M. Crotty, Esquire
Scott W. Parker, Esquire
Ravi V. Sitwala, Esquire
Diana Breau, Esquire
Patterson, Belknap, Webb
& Tyler, LLP
1133 Avenue of the Americas
New York, NY 10036

Courtland L. Reichman, Esquire
King & Spalding
1180 Peachtree Street, NE
Atlanta, GA 30309

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Adam W. Poff (No. 3990)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19899-0391
(302) 571-6600
apoff@ycst.com

*Attorneys for Boston Scientific Corporation
and Boston Scientific Scimed, Inc.*